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| 10/508,746 | 03/19/2005 | Meong-Gun Song | 53850-10100 | 6244 |
| 25226 7590 09/13/2010 MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018 | | | | |
| EXAMINER | | | | |
| MILLER, CHERYL L | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/508,746

Applicant(s)

SONG, MEONG-GUN

Examiner

CHERYL MILLER

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1.5.6.13.15.16.22.23 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13.15.16.23 and 28-30 is/are allowed.
- 6) ☒ Claim(s) 1.5.6.22 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

After Final Amendment

The after final amendment filed August 23, 2010 has been entered as the applicant has incorporated the previous indicated allowable subject matter. However, upon an updated search and further consideration by the examiner, new applicable rejections were found. Thus the finality of the previous rejections mailed July 14, 2010 have been withdrawn and prosecution has been reopened.

The new rejections herein are FINAL.

Priority

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

Currently, the priority date of claims 1, 5, 6, 13, 15, 16, 22, 23, 27-30 is March 26, 2004. If applicant desires to receive a priority date of March 28, 2003, an english translation of the foreign priority document Republic of Korea 10-2003-0019715 is required in order to make this determination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 6, 22, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 line 14 recites, "placement along a *diameter* of an inner surface of the sinotubular junction." This statement is unclear as the figures seem to indicate the ring to be placed along the circumference instead of along a diameter. Claims 5, 6, 22, and 27 depend upon claim 1 and inherit all problems with the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 22, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferrazzi (WO 01/78625 A1, cited previously). Ferrazzi discloses an apparatus for restoring an aortic valve (Ferrazzi's devices have this capability) comprising two discontinuous bands (see fig. 2-6 on left of figs) each having free ends, one of the bands having a thinned region to act as a sewing passage (pg.9, lines 21-25) and two continuous rings (figs.2-4 on right side of figs) capable of placement at the sinotubular junction, one of the rings having a thinned region for suturing (pg.9 lines 21-25). A plurality of rings and bands are disclosed to be provided (see fig.1-8), wherein they may be continuous (right side of figs.2-4 for example) or discontinuous (left side of figs 2-4 for example). As the rings are disclosed to be elastic, they are expandable and contractible to different diameters (see fig.1) and have the capability of fitting within/around an annulus or

sinotubular junction. The rings/bands may comprise a synthetic fiber (dacron, woven covering, pg.9, lines 15-21; fig.11-14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrazzi (WO 01/78625 A1, cited previously). Ferrazzi discloses rings and bands (6, 7, 8; figs.1-8) for supporting vascular lumens substantially as claimed. Ferrazzi discloses the rings and bands may comprise radiopaque markers (pg.10, lines 6-9), which assist in positioning of the implants in the body, however is silent to the locations of these markers. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have three equally spaced markers on the rings or two markers about 2mm from each end of the bands (claimed location of markers), since such is a mere relocation of parts or obvious design choice. In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950). Markers are already disclosed by Ferrazzi to be used on the rings/bands, where they are placed is obvious relocation and would provide predictable results of indicia at these locations.

Claims 1, 5, 6, 22, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lansac (US 2005/0065597 A1, cited previously) in view of Ferrazzi (WO 01/78625 A1, cited previously). Referring to claim 1, Lansac discloses an apparatus comprising an inner

discontinuous band (2; fig.2) having two free ends, and outer discontinuous band (second 2 of another size; Lansac discloses a kit of various sizes, P0014) having two free ends, an inner continuous ring (1; fig.1) and an outer continuous ring (second 1; Lansac discloses a kit of various sizes, P0013) capable of encircling the inside and outside of an STJ (see figs.9-12). Although Lansac only uses bands and rings on the outside of the annulus and STJ (as seen in figs.9-12), Lansac does disclose a plurality of rings and bands provided to the surgeon of various sizes in order to achieve the best fit for a particular patient (P0013, P0014), thus the rings and bands may be considered *capable* of fitting the inside and outside of the annulus and STJ because the sizes are so close and a variety of sizes are provided. Lansac discloses the rings and bands (1 and 2) may be of various cross-sections (P0019), however does not show any of these cross-sections in the figures (thus it is unable to determine if these cross-sections provide thinned regions). Ferrazzi teaches in the same field of rings/bands for supporting vascular lumens (see figs.1-7), the use of thinned regions on any ring or band for the purpose of easier suture attachment to the vessel wall (see figs.11-14 for thinned on covering or pg.9, lines 21-25 for thinned substrate). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Lansac's device having a plurality of rings/bands that may have a different cross-section, with Ferrazzi's teaching of some specific cross-sections having thinner regions, in order to provide Lansac's rings/bands with thinned regions increasing the ease of suture to the vessel.

Referring to claims 22 and 27, Lansac's apparatus does not include a connecting graft (fig.9-12). Lansac discloses the rings/bands to comprise a synthetic fiber (P0041, P0044).

Referring to claims 5 and 6, Lansac discloses rings and bands for supporting vessels, however does not disclose the rings/bands to have markers at the claimed locations. Ferrazzi teaches in the same field of rings/bands for supporting vessels, the use of markers on the rings/bands, in order to provide indication for positioning the devices in the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Lansac's rings/bands with Ferrazzi's teaching of using markers on rings/bands in order to provide Lansac's implant with indicia during positioning of the implants in the body. Ferrazzi discloses the rings and bands may comprise radiopaque markers (pg.10, lines 6-9), which assist in positioning of the implants in the body, however is silent to the locations of these markers. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have three equally spaced markers on the rings or two markers about 2mm from each end of the bands (claimed location of markers), since such is a mere relocation of parts or obvious design choice. In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950). Markers are already taught by Ferrazzi to be used on the rings/bands, where they are placed is obvious relocation and would provide predictable results of indicia at these locations.

Allowable Subject Matter

Claims 13, 15, 16, 23, 28, 29, and 30 are allowed.

It is also noted that previous claim 13 (filed 5/5/2010) would have also overcome the Gabbay rejection (see final 7/14/2010) and be allowable if "proximate" was changed to "along" (along an interior and exterior surface of-not proximate; proximate may be broadly interpreted as

“nearby”) in most portions of the claim. The following claim as of this date is considered allowable by the examiner:

A treatment method for aortic valvular regurgitation associated with an aortic valve having an aortic annulus, an aortic lumen and a sinotubular junction, comprising:

implanting an inner discontinuous band stabilizer inside the aortic lumen along an interior surface of the aortic annulus of the aortic valve,

implanting an outer discontinuous band stabilizer outside the aortic lumen along an exterior surface of the aortic annulus of the aortic valve;

implanting an inner continuous ring stabilizer along an interior surface of the sinotubular junction of the aortic valve; and

implanting an outer continuous ring stabilizer along an exterior surface of the sinotubular junction of the aortic valve.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738

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